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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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JONES DAY
222 EAST 41ST ST
NEW YORK, NY 10017

EXAMINER	
SILVERMAN, ERIC E	

ART UNIT	PAPER NUMBER
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/749,339	AUGSBURGER ET AL.	
	Examiner	Art Unit	
	Eric E. Silverman, PhD	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) *12-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/7/2008 has been entered.

Claims 1 – 38 are pending, claims 12 - 38 are withdrawn, and claims 1 - 11 are treated on the merits in this action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 – 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, upon which claims 2 – 7 now ultimately depend, requires a bead, granule, particle, or pellet comprising an placebo cushioning component and an active loaded particle. Claims 2 - 5 refer to the particle size of the placebo cushioning component. This recitation is indefinite, because the placebo cushioning component is not itself a bead or particle, rater the placebo cushioning component is merely a component of a bead, particle, granule or pellet. It is not clear how a component of a

particle can have a particle size. Claims 6 and 7 refer to the relative amount of the active-loaded particle. This is indefinite because the active-loaded component is merely a part of the bead, granule, particle or pellet that is the claimed product. It is not clear how a component of a bead, granule, particle or pellet can have a particle size.

For the purposes of compact prosecution, claims 2 – 5 are being interpreted to read on the size of the particle, bead, granule or pellet of the invention, and claims 6 and 7 are being interpreted to read on the relative amount of the active agent.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 – 11 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16 - 30 of U.S. Patent No. 5,780,055 to Habib et al. in view of US 4,910,023 to Botzolakis et al. The patented

claims differ from the pending claims in the following ways: (1) Patented claims require a tablet, while pending claims 1 – 10 are generic to the dosage form. Pending claim 10 requires a tablet. Tablets, a species of dosage form, render instant generic dosage forms obvious in their entirety. (2) Patented claims do not recite the exact size ranges for cushioning component particles as instant claims, but patented claim 16 does recite a broad range of sizes that encompass instant ranges. When the general conditions are known, determining the optimal or workable range is obvious. Here, the general limitations of size are claimed in Habib, and the instant claims merely optimize or find the working sizes. (3) Instant claims are generic to the nature of the compactable filler and highly water-absorbing material, whereas patented claims recite specific material for each of these. Patented species claims thus render the pending genus claims obvious in their entirety. (4) Instant claims require that the cushioning component containing particles also contain a drug, whereas the patented claims describe a cushioning particle with microcrystalline cellulose and a disintegrant but no drug. The Botzolakis reference teaches formulating drugs in microcrystaline cellulose particles. Col. 2, lines 10 - 22. The microcrystalline cellulose-drug particles may further comprise disintegrants. Col. 2, lines 55 - 67. The resulting particles have the advantage of being readily compressible into hard tablets, and useful in loading gelatin capsules. Col. 2, lines 55 – 67. It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to load a drug in the cushioning beads of Habib. According to the teachings of Botzolakis, the art recognizes the utility of combining a drug with microcrystalline cellulose and a disintigrant to make particles. Specifically, the

art recognizes that this manipulation results in particles useful for making hard tablets or loading gelatin capsules.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 5 – 11 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,910,023 to Botzolakis et al.

Botolakis discloses a particle composition containing particulate active agent (active loaded particle), microcrystalline cellulose (a highly-compactable filler) and a disintigrant such as povidone (a highly water-absorbing material). Col 2, lines 55 – 67 and Example 2. The particle is made by mixing the ingredients in water and drying. *Id.* Although the products of Botolakis are not freeze-dried (they are dried at temperatures above room temperatures), it appears that the freeze-drying step of the claims and the drying step of the art produce the same result, namely a dry particulate composition. The particles of the art are compressed into tablets. Example 2. The particles of the art have, in Example 2, 53% active particles, 33% microcrystalline cellulose (a highly compactable material) and 6% crospovidone (highly water absorbing material) based on dry weight (the water is driven off during the drying steps). Based on the combined weight of the highly water absorbing material (crospovidone) and the highly compactable filler (microcrystalline cellulose), the crospovidone is about 16% and the microcrystalline cellulose is 84%. 84% reads on "about 80%" in instant claim 9. In Example 1, crospovidone is present in 40% by weight based in the total weight of the crospovidone and microcrystalline cellulose, which reads on the amounts in instant

claims 9 and 10. All of the percentages that are not recited explicitly in the reference are calculated from the masses given in Tables 1 and 2 of the reference.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1 – 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,910,023 to Botzolakis et al as applied to claims 1 and 6 – 11 and in further view of US 5,780,055 to Habib.

What is lacking from Botzolakis are the particle sizes of claims 2 – 4.

Habib teaches particles microcrystalline cellulose and a disintegrant. Claims 16. Habib calls these particles cushioning particles, and suggests they be between 200 microns and 2,000 microns. At col. 65, beads ranging from 14 – 20 mesh (about 841 – 1410 microns) are exemplified. These particles read literally on the sizes of instant claims 2 and 3, and are close enough to 500 microns to be "about 500 microns" as required by instant claim 4. Habib's particles are used in tablets.

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to make the particles of Botzolakis the sizes suggested in

Habib. Obviousness stems from Habib supplying a parameter on which Botzolakis is silent. Because Botzolakis does not mention the size of the particles, the artisan would look to a reference like Habib, which teaches particles having similar ingredients (microcrystalline cellulose and disintegrant) and useful for similar purposes (tablets) to fill in the information on which Botzolakis is silent. The artisan would thus expect to optimize the particle size, and achieve the best possible result.

Claim1 – 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,780,055 to Habib in view of US 4,910,023 to Botzolakis.

Habib teaches particles microcrystalline cellulose and a disintegrant. Claims 16. Habib calls these particles cushioning particles, and suggests they be between 200 microns and 2,000 microns. At col. 65, beads ranging from 14 – 20 mesh (about 841 – 1410 microns) are exemplified. These particles read literally on the sizes of instant claims 2 and 3, and are close enough to 500 microns to be "about 500 microns" as required by instant claim 4. Habib's particles are used in tablets, and are mixed with active loaded (drug) particles to make the final tablet. Claim 16 and col. 65 – 66.

What is lacking from Habib is adding the drug to the cushioning particle, instead of keeping the two separate.

Botolakis discloses a particle composition containing particulate active agent (active loaded particle), microcrystalline cellulose (a highly-compactable filler) and a disintigrant such as povidone (a highly water-absorbing material). Col 2, lines 55 – 67

and Example 2. The particle is made by mixing the ingredients in water and drying. *Id.* The particles of the art are compressed into tablets. Example 2. The particles of the art have, in Example 2, 53% active particles, 33% microcrystalline cellulose (highly compactable material) and 6% crospovidone (highly water absorbing material) based on dry weight (the water is driven off during the drying steps). Based on the combined weight of the highly water absorbing material (crospovidone) and the highly compactable filler (microcrystalline cellulose), the crospovidone is about 16% and the microcrystalline cellulose is 84%. 84% reads on "about 80%" in instant claim 9. In Example 1, crospovidone is present in 40% by weight based in the total weight of the crospovidone and microcrystalline cellulose, which reads on the amounts in instant claims 9 and 10. All of the percentages that are not recited explicitly in the reference are calculated from the masses given in Tables 1 and 2 of the reference.

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to add drug particles to the cushioning particles of Habib. Obviousness stems from the art's recognition that drugs are conveniently released from particles made from the same excipients as those in Habib's cushioning particles (microcrystalline cellulose and disintegrant). Thus, the claims represent no more than a rearrangement of components known in the art to be useable together, wherein each component performs its predictable, art recognized function. The use of cushioning beads is known in Habib, and the use of drugs in beads with the same excipients as the cushioning beads is known in Botolakis. The cushioning component, in the instant invention, still serves its art-recognized functions of cushioning for improved tablet

hardness and releasing a drug; the art recognizes these as properties of the claimed excipients. The artisan would thus enjoy a reasonable expectation of success, because the combination or rearrangement of components is expected to perform (and indeed does perform) the same functions as the components separately.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is (571)272-5549. The examiner can normally be reached on Monday to Thursday 7:00 am to 5:00 pm and Friday 7:00 am to noon.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571 272 0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric E Silverman, PhD/
Examiner, Art Unit 1618